General under this subchapter to manufacture, distribute, or dispense controlled substances or list I chemicals are authorized to possess, manufacture, distribute, or dispense such substances or chemicals (including any such activity in the conduct of research) to the extent authorized by their registration and in conformity with the other provisions of this subchapter.

"**(c) Exceptions**

"The following persons shall not be required to register and may lawfully possess any controlled substance or list I chemical under this subchapter:

"(1) An agent or employee of any registered manufacturer, distributor, or dispenser of any controlled substance or list I chemical if such agent or employee is acting in the usual course of his business or employment.

"(2) A common or contract carrier or warehouseman, or an employee thereof, whose possession of the controlled substance or list I chemical is in the usual course of his business or employment.

"(3) An ultimate user who possesses such substance for a purpose specified in section 802(25) of this title.

"**(d) Waiver**

"The Attorney General may, by regulation, waive the requirement for registration of certain manufacturers,

distributors, or dispensers if he finds it consistent with the public health and safety.

"**(e) Separate registration**

"A separate registration shall be required at each principal place of business or professional practice where the applicant manufactures, distributes, or dispenses controlled substances or list I chemicals."

"**(f) Inspection**

"The Attorney General is authorized to inspect the establishment of a registrant or applicant for registration in accordance with the rules and regulations promulgated by him."

STATEMENT OF THE CASE

A. Trial in the District of South Carolina

This is a criminal case arising out of the District of South Carolina. The district court had jurisdiction pursuant to 18 U.S.C. §3231.

Petitioners worked as physicians at the Comprehensive Care and Pain Management Center ("the Center") in Myrtle Beach, South Carolina. Based on allegations that the Center was a "pill mill" (that is, that the medical practice was a sham and the physicians simply sold prescriptions), petitioners were charged with unlawful distribution of controlled substances, conspiracy to unlawfully distribute controlled substances, and conspiracy to launder money (the physicians' salaries) to promote the operation.

1. Evidence of a crime

Dr. David Woodward established the Center as a neurology and sleep disorder clinic. Over time, Dr. Woodward began prescribing narcotics aggressively. Eventually, Dr. Woodward began selling prescriptions through the Center with no medical pretense. However, Dr. Woodward continued to conduct sham examinations and order other tests, both to conceal the unlawful drug distribution and to collect additional money from insurers.

Following a DEA investigation, the Government indicted eleven employees of the Center, including nine physicians, for crimes including illegal drug distribution, conspiracy to illegally distribute drugs, conspiracy to launder money, money laundering, and health care fraud. Six of the physicians entered into plea agreements with the Government and pleaded guilty to criminal activity. One of those physicians committed suicide after his plea; the other five testified at petitioners' trial. Petitioners tried their cases to a jury in a consolidated trial. The question at trial was whether petitioners participated in Dr. Woodward's scheme.

The court of appeals summarized Dr. Woodward's testimony as follows:

> "According to Dr. Woodward's testimony, CCPMC was simply a front for an illegal prescription-selling operation and a health-care-fraud scheme. * * *.
>
> "Dr. Woodward hired Dr. Jackson in February 1998, and hired Dr. Bordeaux two years later, in February 2000. The evidence revealed that Bordeaux and Jackson, along with other CCPMC physicians, developed a practice known as 'fast tracking,' which they used to expedite the issuance of illegitimate prescriptions for controlled substances. Under the fast-tracking practice, a CCPMC physician

would enter an examination room where five or six patients waited, sign prescriptions for each, and promptly exit without asking any medical questions or performing any medical examinations.

"After Drs. Bordeaux and Jackson left CCPMC in the summer of 2000, Dr. Woodward hired Dr. Alerre. According to Woodward, he needed Alerre to 'shadow' him and issue prescriptions because Woodward's license to prescribe controlled substances had been suspended by the DEA. Woodward further testified that Alerre understood his role before he accepted a position with CCPMC. When Alerre began his work at CCPMC, he would accompany Woodward while superficial patient examinations were conducted. At the conclusion of such examinations, Alerre would issue illegitimate prescriptions to the patients.

"* * * * *

"Importantly, Dr. Woodward also testified that he confronted each defendant and inquired whether they understood the illicit nature of CCPMC's activities. The defendants assured Woodward that they were willing to participate in CCPMC's overall scheme. Woodward approached Dr. Jackson, asked if he was 'able to do this,' and Jackson assured him 'I got your back.' In answering a similar inquiry, Dr. Bordeaux replied 'if I go along with this and do this, can I have your father's pickup truck?' When Woodward asked Dr. Alerre if he was comfortable with 'what we were doing,' Alerre paused and responded '[o]h, to hell with it.' Woodward understood Alerre's response to confirm that Alerre was 'part of our team'; that is, Alerre was

agreeing to join in Woodward's illicit operations."

United States v. Alerre, 430 F.3d 681, 684-86 (CA4 2005); Pet. App. 5a-8a (internal footnotes and citations to record omitted).

Dr. Bordeaux worked at the Center for three months, Dr. Alerre worked at the Center for eight months, and Dr. Jackson worked at the Center for two years.

2. Evidence of no "legitimate medical purpose"

The Government also presented expert testimony regarding petitioners' medical practices that it claimed proved petitioners' guilt. On the second day of an 11-day trial, the issue of "legitimate medical purpose" arose. The Government argued that "part of the charge is, if medicine is prescribed * * * for other than legitimate medical purposes." J.A. 282.[1] When the district court asked if that was part of the statute, the Government answered: "Yes, sir, that is an issue, it's part of the statute." From that point on, the Government's presentation of evidence and legal arguments to the jury focused on the Government's interpretation that a lack of a "legitimate medical purpose" proved the crime.

For example, on the third day of trial the Government elicited evidence that certain prescriptions were not "medically necessary." J.A. 359-60. When the district court questioned whether medical necessity proved whether a prescription was issued outside the course of professional practice, the Government answered:

"Prosecutor: [The expert witnesses]

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[1]References to the Joint Appendix (J.A.) in this petition refer to the Joint Appendix filed in the Fourth Circuit.

> are going to say [the defendants] did not follow the proper procedure. * * *. They are allowed to write these prescriptions if they are medically necessary. If it's not medically necessary –
>
> "The Court: Does the statute say medically necessary?
>
> "Prosecutor: Yes, sir. We tracked the statute in the indictment. If it's medically necessary, they haven't done anything wrong. If it's not medically necessary, they are drug dealing. So that's a huge issue, Your Honor. It could be the whole issue."

J.A. 361-62.

The prosecutor subsequently called an expert witness who testified in accordance with the Government's view on legitimate medical purposes. The witness testified for two days, reviewing medical charts of the Center's patients and offering an opinion based on "the quality of care." J.A. 900. The Government's expert witness understood "outside the course of professional practice" to mean not "legitimate medical practice," which he defined on one occasion as "the dosages that a prudent physician in the state of South Carolina would give, as what we call the standard of care" (J.A. 815-16, emphasis added), and on another occasion as "a case wherein an understanding exists between the physician and the patient to provide the best possible medical services, and that those prescriptions and services be based upon a documented logical disease process, which requires that medication" (J.A. 818, emphasis added). Based on that understanding of "legitimate medical purpose," the witness offered two days of expert testimony that petitioners' actions were "outside the scope of professional practice" and thus criminal, based on his conclusion that petitioners' practices deviated from the civil standard of care or were not the "best possible" services and therefore did not have a "legitimate medical purpose" as he defined

that term. See J.A. 726-76, 789-970 (Dr. Jordan's expert testimony).

Similarly, petitioners' trial attorneys defended their cases as though the quality of medical practices controlled. Petitioners' defense attorneys focused on guidelines for treatment and dosing, standards of practice, and the quality of petitioners' treatment practices. *See, e.g.*, J.A. 830-97, 898-927, 937-59 (cross-examination of Government's expert witness by petitioners' defense attorneys, illustrating focus on adequacy of medical practices). Petitioners' defense attorneys did not frame the evidence or their legal arguments to emphasize that petitioners were guilty of unlawful drug distribution only if they abandoned their roles as physicians and acted as drug dealers; rather, the defense attorneys tried the case on the adequacy of petitioners' medical practices.

At the conclusion of the trial, petitioners were convicted of unlawful drug distribution (in three counts against Dr. Bordeaux, seven counts against Dr. Alerre, and five counts against Dr. Jackson), conspiracy to unlawfully distribute controlled substances, and conspiracy to launder money.

B. Origin of the "legitimate medical purpose" interpretation of 21 U.S.C. §841(a)

As detailed above, the Government argued that the regulatory language "legitimate medical purpose" equated with the statutory language "outside the course of professional practice." The Government defined a "legitimate medical purpose" not in terms of conventional drug dealing, but in terms related to the adequacy, propriety, or necessity of the medical practices employed. Therefore, the Government argued, "the whole issue" under the statute could be resolved by whether the prescription was issued "for other than legitimate medical purposes." *E.g.*, J.A. 282, 362.

Similar arguments have been made in drug prosecutions against physicians across the country, as

discussed later in this petition. The origin of the interpretation underlying that argument, and its recurrence in prosecutions in different circuits throughout the country, may be explained by the Department of Justice's publication of a single national source document

In 2002, as petitioners were indicted and trial preparation was conducted in this case, DOJ published on its website a Quick Reference Card intended to "serve as a basic guide to prosecuting prescription drug diversion cases." Quick Reference Card, J.A. 1300, Pet. App. 38a-50a. The Quick Reference Card cites 21 C.F.R. §1306.04 for the legitimate medical purpose rule, then provides: "Any individual practitioner who issues or fills a prescription knowing that the prescription was not issued for a legitimate medical purpose in the usual course of professional treatment (or for legitimate and authorized research), shall be subject to penalties provided for violations of the controlled substances law." Pet. App. 41a. Having thus defined the crime to include a "legitimate medical purpose" element, the Quick Reference Card further defines that element as follows:

> "**What is a legitimate medical purpose?**
> "A physician is acting with a legitimate medical purpose when he or she prescribes medical treatments that are in **strict compliance with well-established and generally accepted medical guidelines, and administers medical treatments that appropriately and correctly address and relieve the present medical condition.**"

Pet. App. 42a (bold print in original).[2]

By this logic, the Government interprets 21 U.S.C.

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[2]The Quick Reference Card has been removed from DOJ's website.

§841(a) to include its interpretation of the language "legitimate medical purpose" in 21 C.F.R. §1306.04, and thus to criminalize any deviation from "strict compliance with well-established and generally accepted medical guidelines."[3]

C. Appeal in the Fourth Circuit Court of Appeals

Petitioners appealed, arguing that prosecutorial misconduct and ineffective assistance of counsel--each committed when the prosecutor and the defense attorneys applied the Government's interpretation of 21 C.F.R. §1306.04, instead of the statutory language, as the criminal standard--denied them a fair trial. Petitioners argued that, in fact, unlawful drug distribution under 21 U.S.C. §841(a) does not have a legitimate medical purpose element. Petitioners likened the Government's interpretation to criminalizing malpractice and argued that the Government committed prosecutorial misconduct under *Berger v. United States,* 295 U.S. 78 (1935)[4], by improperly casting malpractice as a crime throughout the trial. Petitioners further argued that their defense attorneys were ineffective for failing to identify and object to the Government's erroneous interpretation and for improperly defending them under that interpretation.[5]

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[3]In South Carolina, where petitioners were licensed to practice medicine, malpractice is defined as a deviation from "recognized and generally accepted standards, practices, and procedures" in the physician's field of medicine. *Gooding v. St. Francis Xavier Hosp.*, 326 S.C. 248, 254, 487 S.E.2d 596 (1997).

[4]*Berger* was overruled on other grounds by *Stirone v. United States*, 361 U.S. 212 (1960).

[5]That is, petitioners' defense attorneys accepted the Government's interpretation of 21 U.S.C. §841(a) and framed their evidence and arguments to defend against the claims of

The Government responded that unlawful drug distribution does criminalize malpractice, and properly so. In the Government's view, "[t]he 'course of professional practice' element corresponds generally to the standard of care in civil malpractice actions." Appellee's Brief 15, 26. That is so, the Government argued, because "[t]he regulatory term 'legitimate medical purpose' and the statutory term 'course of professional practice' are virtually identical." Appellee's Brief 22-23. The Government reasoned that physicians are protected against the risk of a criminal conviction based on a civil standard of liability by the requirement that criminal cases be proved beyond a reasonable doubt. Appellee's Brief 15, 27. That is, according to the Government, when malpractice by a prescribing physician is proved beyond a reasonable doubt, it is criminal drug dealing.

The court of appeals affirmed petitioners' convictions.[6] The court held that, because there was sufficient evidence of a crime and the district court properly instructed the jury on the elements of the crime, petitioners' challenge to the parties' conduct at trial "does not pass muster." 430 F.3d at 691 (Pet. App. 22a). The court "decline[d] to reach and address the defendants'

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deficient medical practices. Petitioners' defense attorneys never argued to the jury that it should acquit unless it found that petitioners had abandoned the practice of medicine in favor of drug dealing; instead, petitioners' defense attorneys argued that the jury should acquit if it found that petitioners adhered to the general standards of medical practice. However, the jury did not need to find so much to acquit petitioners of drug dealing. The defense attorneys defended only against the allegations of malpractice (*i.e.*, deviating from the standard of care); they were ineffective in failing to present a defense against the actual crime of drug dealing.

[6]The court remanded for resentencing in light of *United States v. Booker*, 543 U.S. 220 (2005).

ineffective assistance claims, and * * * reject[ed] their prosecutorial misconduct claims on the merits." *Id.* at 692 (Pet. App. 24a).

The court of appeals denied petitioners' petition for rehearing or rehearing en banc. Pet. App. 34a-35a.

REASONS FOR GRANTING THE PETITION

This case presents an important question of federal law that has not been, but should be, settled by this court. As explained below, the issues have national significance and national implications. The issue is unlikely to be resolved by the circuit courts. The question is deserving of an answer from this Court.

I. The Government is enforcing an invalid interpretation of 21 U.S.C. §841(a), based on its interpretation of 21 C.F.R. §1306.04, in prosecutions of physicians.

A. The Government interprets 21 U.S.C. §841(a) to include deviations from generally accepted medical practices (*i.e.*, malpractice).

This case is a counterpart to *Gonzales v. Oregon*, 546 U.S. __, 126 S.Ct. 904 (2006).[7] Like *Gonzales*, it involves the interplay between the Controlled Substances Act ("CSA") and 21 C.F.R. §1306.04(a) (the "legitimate medical purpose regulation" or "the regulation"), and like *Gonzales*, its resolution requires "interpreting a federal statute to determine whether Executive action is authorized by, or otherwise consistent with, the enactment." 126 S.Ct. at 911. Here, however, the problem arises in a different context.

Where *Gonzales* involved the Attorney General's

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[7]Petitioners' counsel also served as counsel of record for the physician and the pharmacist in *Gonzales v. Oregon*.

Interpretive Rule, which interpreted the regulation to criminalize physician-assisted suicide, here the Executive action at issue is the Department of Justice's interpretation of the regulation, which purports to criminalize malpractice by defining the crime of unlawful drug distribution as a violation of the civil standard of care. *Gonzales* involved a federal rule; here the interpretation serves as a guide to the prosecution of individual cases nationwide.

Where *Gonzales* had a clean and simple factual context--the state of Oregon authorized physicians to prescribe controlled substances to assist a terminal patient in hastening his or her death, and the Attorney General issued a Rule declaring such action a crime--in this case, and others like it, the factual context is more complex. In these cases, the physicians are accused of unlawful drug distribution, which Congress has defined as a crime, and there is some evidence of the activity Congress sought to criminalize. (Here, for example, Dr. Woodward testified that the Center was a sham and that the Center's physicians, including petitioners, sold prescriptions with no pretense of medical practice.) However, the prosecutor and, in many cases, the defense attorneys, do not force the jury to judge that evidence. Rather, the parties present a substantial amount of evidence on the quality of the physician's medical practices, and tell the jury that the physician may be found guilty of the crime if his or her medical practices did not conform to the standard of care.[8] That, however, is not the activity that Congress criminalized. The result is a general verdict of guilt that does not identify whether the jury found that the physician was a drug dealer or

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[8]In this case, for example, the Government's expert witness so informed the jury in plain terms. The expert testified that "outside the course of professional practice" meant without a "legitimate medical purpose," which in turn meant that the physician did not conform to the "standard of care" applicable in civil actions.

that the physician committed malpractice.

Despite the Government's argument that either is acceptable, the latter is not. Congress did not criminalize malpractice. The Department of Justice did not have the authority to criminalize malpractice, as it attempted to do through the interpretation published in the Quick Reference Card and applied in this and other prosecutions. Petitioners' verdicts cannot stand. However, because there is some evidence of a crime, the court of appeals let the verdict stand, despite the Government's reliance on its "legitimate medical purpose" theory of conviction. An announcement from this Court, enforcing only Congress' definition of drug dealing, is required to afford petitioners and other similarly situated physicians a fair trial on the charge of unlawful drug distribution.

B. Evolution of reliance on the phrase "legitimate medical purpose"

The CSA was enacted by Congress in 1970 "with the main objectives of combating drug abuse and controlling the legitimate and illegitimate traffic in controlled substances." *Gonzales v. Oregon*, 126 S.Ct. at 911, citing *Gonzales v. Raich*, 545 U.S. __, 125 S.Ct. 2195, 2203 (2005). Congress, through the CSA, "regulates medical practice insofar as it bars doctors from using their prescription-writing powers as a means to engage in illicit drug dealing and trafficking as conventionally understood. Beyond this, however, the statute manifests no intent to regulate the practice of medicine generally." *Gonzales v. Oregon*, 126 S.Ct. at 923.

In *United States v. Moore*, 423 U.S. 122 (1975), this Court considered whether a physician is *per se* exempted from prosecution under 21 U.S.C. §841(a) because of his status as a registrant. *Id.* at 131. The Court answered no: "only the lawful acts of registrants are exempted." *Id.* The Court explained that the legislative history of the CSA revealed that a violation of the CSA "was intended to turn on whether the

'transaction' falls within or without legitimate channels." *Id.* at 135. The Court observed that "'severe criminal penalties' were imposed on those, like [Moore], who sold drugs, not for legitimate purposes, but 'primarily for the profits to be derived therefrom.'" *Id.*, quoting H.R.Rep.No.91-1444, p. 10, U.S.Code Cong. & Admin.News 1970, p. 4569. Therefore, a physician may prescribe drugs "only to act 'as a physician.'" *Id.* at 141. Where, as in *Moore*, the physician "acted as a large-scale 'pusher' not as a physician," criminal liability follows. *Id.* at 143.

Moore is often cited for its holding that the CSA prohibits a physician from acting as a drug pusher. *See, e.g., Gonzales v. Oregon*, 126 S.Ct. at 922 ("It comes as little surprise, then, that we have not considered the extent to which the CSA regulates medical practice beyond prohibiting a doctor from acting as a drug 'pusher' instead of a physician. *Moore*, 423 U.S., at 143." *Moore* also engendered, however, reliance on the phrase "legitimate purposes."

In *United States v. Daniel*, 3 F.3d 775 (CA4 1993), a physician was indicted for attempting to violate 21 U.S.C. §841(a). The indictment recited that the physician "did knowingly and intentionally unlawfully attempt to dispense or distribute a quantity of a Schedule II Controlled Substance * * *; said attempt not being for a legitimate medical purpose." *Id* .at 777-78. The defendant challenged the indictment, arguing that it failed to charge three essential elements: "(1) action outside the usual course of medical practice, (2) action not in good faith and proper accordance with a standard of medical practice generally recognized and accepted in the United States, and (3) action by a practicing physician." *Id.* at 778.

The Fourth Circuit rejected the challenge to the indictment. The court of appeals noted that registered physicians may dispense controlled substances "to the extent authorized by their registration and in conformity with the other provisions of this subchapter." *Id.*, quoting 21 U.S.C. §822(b). The court observed: "In *United States*

v. Moore, the Supreme Court limited this authority to distributions and dispensations in the lawful course of approved professional practice." *Id.* (citation omitted). The court held:

> "As we interpret the statute, its elements are (1) a knowing or intentional attempt to distribute or dispense (2) a substance known to be controlled (3) in a way not authorized by this subchapter. All [defendant's] complaints relate to the third element recited. With respect to physicians, demonstrating that element requires proof that the charged conduct falls outside the boundaries of the registrant's professional practice. *Moore*, 423 U.S. at 140, 96 S.Ct. at 344. The indictment's allegations that the attempted distributions or dispensations were 'not ... for a legitimate medical purpose' satisfy that requirement. No more is necessary. The first two of [defendant's] 'missing elements' simply repeat this requirement in other, less concise, terms. The third, that Daniel was a physician, need not be proven by the government. On the contrary, it is the source of the requirement that the government show a lack of legitimate medical purpose at all. Accordingly, we find the indictment sufficient."

Id. (emphasis added). Thus, the court held that "not for a legitimate medical purpose" was a more precise way of saying "outside the course of professional practice." As demonstrated below, however, substituting another phrase for the statutory language did not lead to more precision, but rather led the courts and prosecutors alike away from Congress' intent.

In *United States v. Tran Trong Cuong*, 18 F.3d 1132 (CA4 1994), the defendant argued that the district

court and the prosecution had used a medical malpractice standard rather than the criminal standard to judge his actions. *Id.* at 1137. The court of appeals acknowledged that the two standards were confused at times, citing references to what "a reasonably prudent physician would do" and to the "standard of care of a family practitioner." *Id.* The court stated:

> "A criminal prosecution requires more--that is, proof beyond a reasonable doubt that the doctor was acting outside the bounds of professional medical practice, as his authority to prescribe controlled substances was being used not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose, *i.e.* the personal profit of the physician."

Id. Thus, the court of appeals defined the criminal element "outside the course of professional practice" as "assisting another in the maintenance of a drug habit" or "dispensing controlled substances for other than a legitimate medical purpose." *Id.*

The court of appeals noted that the district court had instructed the jury on the "third element, no legitimate medical purpose." *Id.* The court of appeals held that the jury was properly instructed:

> "The instructions given the jury include a satisfactory definition of the actions of a physician which are outside the course of professional medical practice. The standard used by the court 'without a legitimate medical purpose' does appear to be more strict than that required by *Moore* and therefore was to defendant's benefit."

Id. at 1138.

The following year, in *United States v. Singh*, 54 F.3d 1182 (CA4 1995), the Fourth Circuit quoted *Tran Trong Cuong* with approval for the proposition that, "§841(a) was violated when the doctor's 'authority to prescribe controlled substances was being used not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose.'" *Singh*, 54 F.3d at 1188-89, quoting *Tran Trong Cuong*, 18 F.3d at 1137.

Recently, in *United States v. Hitzig*, 63 Fed.Appx. 83 (CA4 2003) (unpublished), the Fourth Circuit held that the Government may prove that a physician unlawfully distributed drugs by establishing either that the physician's actions were not for a legitimate medical purpose, or that they were beyond the bounds of professional medical practice. *Id.* at 86, citing *Singh*, *Tran Trong Cuong*, and *Daniel*.

These cases demonstrate that the Fourth Circuit has permitted the substitution of the phrase "not for a legitimate medical purpose" for the element "outside the course of professional practice," reasoning that the former is more precise or offers more protection to the defendant than the statutory language.

The reliance on a "legitimate medical purpose" in drug prosecutions of physicians in not unique to the Fourth Circuit. *See, e.g.*, *United States v. Nelson*, 383 F.3d 1227, 1231-32 (CA10 2004) ("A practitioner has unlawfully distributed a controlled substance if she prescribes the substance either outside the usual course of medical practice or without a legitimate medical purpose"; citing *Moore* and 21 C.F.R. §1306.04, "the governing regulation"); *United States v. Pedrick*, 181 F.3d 1264, 1268 n 8-(CA11 1999) ("Under 21 U.S.C. §841(a)(1) and 21 C.F.R. §1306.04, it is illegal for a practitioner * * * to issue a prescription for a controlled substance without a legitimate medical purpose and outside the usual course of his professional practice"); *United States v. Ekinci*, 101 F.3d 838 (CA2 1996) (characterizing crime under 21 U.S.C. §841(a) as distributing controlled

substances "without a legitimate medical purpose" and upholding conviction based on indictment and jury instructions phrased in those terms, with no challenge to or discussion of variance from statutory language); *United States v. Kirk*, 584 F.2d 773, 784 (CA6 1978), *cert. denied*, 439 U.S. 1048 (stating: "It has been held that there is no difference in the meanings of the statutory phrase, 'In the usual course of professional practice" and the regulations' phrase, 'legitimate medical purpose,'" citing *United States v. Plesons*, 560 F.2d 890, 897 (CA8 1977), *cert. denied,* 434 U.S. 966, and *United States v. Rosenberg*, 515 F.2d 190, 197 (CA9 1975), *cert. denied*, 423 U.S. 1031; and subsequently quoting 21 U.S.C. §841(a)(1) and 21 C.F.R. §1306.04(a) in support).

However, the Government's interpretation of a "legitimate medical purpose," as applied in this case, as defined in the Quick Reference Card, and as applied in other pending cases (discussed below), does not have the same meaning as the statutory language and does not work to the defendant-physician's benefit. To the contrary, the Government's interpretation lowers the Government's burden of proof.

Under the Government's interpretation, a physician acts without a legitimate medical purpose when he or she acts without "proper procedures" and "medical necessity" (as defined by the Government in this case) or without "strict compliance with well-established and generally accepted medical guidelines" (as defined by the Government in the Quick Reference Card). Notably, neither of those definitions even proves civil malpractice, which does not require strict compliance with the standard of care or medical necessity. More importantly, neither of those definitions proves a crime under 21 U.S.C. §841(a).[9]

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[9]There is a distinction to be made between the Government's argument that a deviation from proper procedures or generally accepted medical guidelines proves the crime, and case law recognizing that deviations from general

Yet the Government defends its interpretation, even as it acknowledges that its interpretation works to criminalize malpractice, by asserting that a verdict on that ground is proper so long as it is found beyond a reasonable doubt. Appellee's Brief 15, 22-23, 26-27.

As defined by Congress and as interpreted by this Court in *Moore*, 21 U.S.C. §841(a) criminalizes a physician's distribution of controlled substances when the physician ceases to "act 'as a physician'" and acts instead as a drug "pusher." *Moore*, 423 U.S. at 141, 143. Under the Government's interpretation, however, the Government does not need to prove that the physician ceased to act as a physician; the Government only needs to prove that the physician acted as a bad, or civilly negligent, physician. But that interpretation runs counter to Congress' intent to "conquer drug abuse and to control the legitimate and illegitimate traffic in controlled substances." *Raich*, 125 S.Ct. at 2203. It is the physician's specific action of ceasing to act as a physician, instead acting as a drug seller or trafficker, that defines the crime.

Therefore, the Government's interpretation of "legitimate medical purpose" does not conform to the statutory language or purpose, and permits conviction on insufficient proof of a crime. However, because court of appeals case law has incorporated the "legitimate medical purpose" language into the statute, the Government has succeeded in enforcing its definition of the crime.

This Government action is not consistent with the CSA. As this Court recognized in *Gonzales v. Oregon*,

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medical practices may establish that the defendant ceased to act as a physician and instead acted as a mere drug seller, which proves the crime. Where the jury concludes that the defendant ceased to act as a physician and acted as a mere drug seller, a guilty verdict for a drug crime is proper and supportable. Where the jury concludes only that the physician failed to follow general standards of practice, such finding is insufficient to support a conviction for a drug crime.

Congress did not delegate to the Attorney General (or to DOJ) the authority to define what is criminal under the CSA. 126 S.Ct. at 918. The regulation does not change the statutory language, or what the statute means. The Government's enforcement of its interpretation of "legitimate medical purpose" to criminalize malpractice is invalid.

In sum, the question in this case is whether the Government's action in applying its interpretation of the legitimate medical purpose regulation in the trials of registered physicians is consistent with the CSA and affords a fair trial on the charge of unlawful drug distribution. The answer is no.

II. The error is pervasive and widespread.

As noted above, the error in supplanting the test for criminality with the civil standard of care is systemic, and may be traced to the Department of Justice's Quick Reference Card. Petitioners are aware of several cases in which the prosecution of a physician for unlawful drug distribution focused on alleged deficiencies in the physician's medical practices, with the argument that medical practices that did not comply with generally accepted practices evidenced an absence of legitimate medical purpose, which proved the crime. The following cases, in which petitioners' counsel consulted or served as counsel and challenged the Government's action in so arguing, are illustrative.

In *United States v. Bernard Rottschaefer*, Third Circuit Court of Appeals Case Nos. 04-4015 and 05-1229, the Government responded to the physician's challenge on appeal by asserting that Dr. Rottschaefer had "completely ignore[d] the 'legitimate medical purpose' element of the offense." *U.S. v. Rottschaefer*, Appellee's Brief 35. The Government relied on the regulation (21 C.F.R. §1306.04) to argue that the crime of unlawful drug distribution under 21 U.S.C. §841(a) could be proved by lack of a legitimate medical purpose:

> "When the CSA went into effect, the DEA's predecessor issued regulations to implement the Act. One of those regulations requires that a prescription 'must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.' 21 C.F.R. §1306.04(a) (emphasis added). A prescription that is not issued for a legitimate medical purpose is simply not a 'prescription' under the Act. If issued knowingly, such a prescription will subject the practitioner 'to the penalties provided for violations of law relating to controlled substances.' *Id.* As the Supreme Court stated in *United States v. Moore*, this legitimate medical purpose requirement is implicit in various provisions of the CSA, but it is made explicit by the DEA regulation, 21 C.F.R. §1306.04(a). *United States v. Moore*, 423 U.S. 122, 137-39 & n.13 (1975)."

U.S. v. Rottschaefer, Appellee's Brief 33-34 (emphasis in original). The Government cited *United States v. Norris*, 780 F.2d 1207, 1209 (CA5 1986), *United States v. Polan*, 970 F.2d 1280, 1282 (CA3 1992), *United States v. Vamos*, 797 F.2d 1146, 1151-53 (CA2 1986), and *United States v. Nelson*, 383 F.3d 1227, 1230-33 (CA10 2004), in support of its argument that the third element of the crime is a "legitimate medical purpose element."

Rottschaefer was argued March 3, 2006, and is currently under advisement in the Third Circuit.

In *United States v. Feingold*, Ninth Circuit Court of Appeals Case No. 05-10037, the defendant-physician challenged the Government's reliance on "legitimate medical purposes" and attendant arguments that deficient medical practices proved unlawful drug distribution. The Government responded that the

physician misrepresented the holding of *Moore*:

> "Contrary to defendant's argument, however, the Court did not proceed * * * to determine that the phrase 'outside the course of professional practice,' for purposes of a conviction under the CSA, specifically means 'for intentional diversion to illegitimate channels.'"

U.S. v. Feingold, Appellee's Brief 24. Rather, the Government argued, the physician is subject to a "legitimate medical purpose" requirement to avoid criminal liability, because the Ninth Circuit's "reading of * * * *Moore* suggests that the 'usual course' standard itself imports considerations of medical legitimacy and accepted medical standards." *U.S. v. Feingold*, Appellee's Brief 25, quoting *United States v. Boettjer*, 569 F.2d 1078, 1081 (CA9 1978).

Feingold is sheduled for oral argument on April 4, 2006, before the Ninth Circuit Court of Appeals.

In *United States v. McIver*, Fourth Circuit Court of Appeals Case No. 05-4884, the Government not only argued the case to say that a deviation from generally accepted medical practices proved the crime, it convinced the district court to instruct the jury on that theory. On the Government's request, the court instructed the jury:

> "In determining the defendant's – whether the defendant's conduct was within the bounds of professional practice you should, subject to the instructions I give you concerning the credibility of experts and other witnesses, consider the testimony you have heard relating to what has been characterized during the trial as the norms of professional practice.
>
> "You should also consider the extent to which, if at all, any violation of professional norms you find to have been

> committed by the defendant interfered with his treatment of his patients and contributed to an over prescription and/or excessive dispensation of controlled substances. You should consider the defendant's actions as a whole and the circumstances surrounding them."

U.S. v. McIver, Appellant's Brief 30, citing J.A. 1243-44. The Government responded that the instruction was proper, relying heavily on the Fourth Circuit's opinion in petitioners' case. Appellee's Brief 20-23, citing *U.S. v. Alerre*, 430 F.3d 681 (CA4 2005).

Briefing was completed in *McIver* on February 28, 2006. Oral argument has not yet been scheduled.

In *United States v. Williams*, Eleventh Circuit Court of Appeals Case No. 04-15117G, the physician raised the same arguments, practically verbatim, as those raised in the Fourth Circuit in this case (after consultation with petitioners' counsel and giving due credit) in his appellant's brief. *Williams* was argued January 31, 2006, and is currently under advisement in the Eleventh Circuit Court of Appeals.

III. The error is unlikely to be corrected by the circuit courts.

In this case, the court of appeals did not address the legality of the Government interpreting 21 U.S.C. §841(a) to include a "legitimate medical purpose" element and applying that interpretation in its prosecution of physicians such as petitioner. That is, the Fourth Circuit did not squarely address whether the Government or petitioners' trial counsel improperly tried the case. Rather, the court found no reversible error, owing to a legal presumption that prevents the court from looking beyond the jury instructions.

The court acknowledged that "[t]o be sure, an undue emphasis on standard-of-care evidence might, in certain circumstances, confuse a jury." *United States v.*

Alerre, 430 F.3d at 691 n 10 (Pet. App. 22a). However, the court held:

> "The jury entered its deliberations armed with ample admissible evidence and with proper instructions on the applicable legal principles. The defendants' assertions that their lawyers were confused at trial is insufficient to rebut the presumption that the jury used those tools properly. [FN 11]
>
> > "FN11. Even if the defendants could show error with respect to their standard-of-proof assertions, it would be difficult to conclude that they were thereby prejudiced. Indeed, Dr. Woodward's testimony alone was sufficient to convict the defendants, and it was supported by other evidence. And in light of its verdict, we assume that the jury credited Woodward's testimony. *See United States v. Hughes*, 401 F.3d 540, 544-45 (4th Cir 2005)."

Id. at 692 (Pet. App. 23a-24a). The court thus "decline[d] to reach and address the defendants' ineffective assistance claims, and * * * reject[ed] their prosecutorial misconduct claims on the merits." *Id.* (Pet. App. 24a).

The court presumed that the jury followed the district court's instructions and relied upon the proper evidence to convict. That legal presumption obviated the need to further analyze the prosecutor's and the defense attorneys' reliance on the wrong legal standard. Without that legal presumption, reversal would have been warranted, because when a jury is presented with two theories of conviction, one of which is legally infirm, and the verdict does not reveal the theory on which the jury relied, the conviction cannot stand. *Yates v. United States*, 354 U.S. 298, 312 (1957), *overruled on other*

grounds by Burks v. U.S., 437 U.S. 1 (1978) ("In these circumstances we think the proper rule to be applied is that which requires a verdict to be set aside in cases where the verdict is supportable on one ground, but not on another, and it is impossible to tell which ground the jury selected.") (citations omitted). The Sixth Amendment does not permit an appellate court to sit in the place of the jury and to presume a verdict which the jury did not find. As stated in *Sullivan v. Louisiana*, 508 U.S. 275 (1993):

> "The inquiry, in other words, is not whether, in a trial that occurred without the error, a guilty verdict would surely have been rendered, but whether the guilty verdict actually rendered in *this* trial was surely unattributable to the error. That must be so, because to hypothesize a guilty verdict that was never in fact rendered--no matter how inescapable the findings to support that verdict might be--would violate the jury-trial guarantee."

Id. at 279 (emphasis in original).

Consequently, the question whether the Government strikes a "foul blow" or uses "improper methods calculated to produce a wrongful conviction"[10] by arguing that 21 U.S.C. §841(a) criminalizes a physician's conduct in the absence of a "legitimate medical purpose" is unlikely to be resolved by the circuit courts. The circuit courts will continue to apply "the almost invariable assumption of the law that jurors follow their instructions,"[11] and the substantive question will continue

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[10] *Berger*, 295 U.S. at 88.

[11] *Richardson v. Marsh*, 481 U.S. 200, 206-07 (1987) (citing examples of the "many varying contexts" in which the assumption is applied).

to evade meaningful review.

IV. Summary

In short, the Government used the regulation to establish a new definition of the crime of unlawful drug distribution. That it could not do. *Gonzales*, 126 S.Ct. at 918. Nevertheless, both the prosecution and the defense tried petitioners' case under that erroneous definition. Physicians throughout the country have been similarly tried under the erroneous Government definition. The error is entrenched.

Because petitioners and other physicians face prosecutions and criminal drug distribution convictions that may rest on substandard medical practices, review is warranted. This case presents the Court an opportunity to announce that a criminal conviction cannot be had based on substandard medical practices claimed to violate the regulation and thus the CSA.

CONCLUSION

Petitioners respectfully urge this Court to grant the petition for a writ of certiorari.

Respectfully submitted,

ELI D. STUTSMAN
Counsel of Record
MONICA L. FINCH
621 SW Morrison Street
Thirteenth Floor
Portland, OR 97205-3816
(503) 274-4048

March 28, 2006

APPENDIX

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

PUBLISHED
UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

United States of America,
Plaintiff-Appellee,
v. No. 03-4207
Ricardo U. Alerre,
Defendant-Appellant.

United States of America,
Plaintiff-Appellee,
v. No. 03-4212
Deborah Bordeaux,
Defendant-Appellant.

United States of America,
Plaintiff-Appellee,
v. No. 04-4161
Michael D. Jackson,
Defendant-Appellant.

Appeals from the United States District Court
for the District of South Carolina, at Florence.
C. Weston Houck, Senior District Judge.
(CR-02-673)

Argued: September 20, 2005

Decided: December 1, 2005

Before MICHAEL, MOTZ, and KING, Circuit Judges.

United States v. Alerre

Affirmed in part, vacated in part, and remanded by published opinion. Judge King wrote the opinion, in which Judge Michael and Judge Motz joined.

COUNSEL

ARGUED: Eli D. Stutsman, Portland, Oregon, for Appellants. Thomas Ernest Booth, UNITED STATES DEPARTMENT OF JUSTICE, Washington, D.C., for Appellee. ON BRIEF: G. Wells Dickson, Jr., Charleston, South Carolina, for Appellant Deborah Bordeaux; Lionel S. Lofton, Charleston, South Carolina, for Appellant Ricardo U. Alerre; David Bruce Betts, Columbia, South Carolina, for Appellant Michael D. Jackson. Jonathan S. Gasser, Acting United States Attorney, William E. Day, II, Assistant United States Attorney, OFFICE OF THE

UNITED STATES ATTORNEY, Columbia, South Carolina, for Appellee.

OPINION

KING, Circuit Judge:

Appellants Ricardo U. Alerre, Deborah S. Bordeaux, and Michael D. Jackson (the "defendants") challenge the various convictions and sentences imposed on them in the District of South Carolina. The defendants – medical doctors – seek a new trial on drug distribution, drug conspiracy, and money-laundering conspiracy charges levied against them by the grand jury. The multiple charges in their indictment arise from an alleged prescription-selling operation and a health-care-fraud scheme carried out during a four-year period in the Myrtle Beach area of South Carolina. The defendants contend on appeal that, in their 2003 trial, their lawyers were constitutionally ineffective and the prosecutors engaged in prejudicial misconduct. They also maintain that the trial evidence was insufficient to support their money-laundering conspiracy convictions. Finally, the defendants challenge their sentences on the basis of the Supreme Court's recent decision in *United States v. Booker*, and the prosecutors have confessed error on that point. As explained below, we affirm the defendants' convictions, vacate their sentences, and remand for resentencing.

I.

The Government prosecuted the defendants – who were medical doctors licensed in South Carolina and registered with the Drug Enforcement Administration (the "DEA") – for their involvement with the Comprehensive Care and Pain Management Center ("CCPMC"), in Myrtle Beach. During the relevant period (1997 to 2001), CCPMC was owned and operated by Dr. David Woodward. On August 29, 2002, the grand jury charged the defendants, along with Woodward and four others, in a ninety-three count indictment. J.A. 83-110.[1] The defendants were each charged with conspiracy to distribute controlled substances, in contravention of 21 U.S.C. § 846 (the "drug conspiracy charge") (Count 1); conspiracy to commit money laundering, in violation of 18 U.S.C. § 1956(h) (the "laundering conspiracy charge") (Count 93); and multiple counts of distributing controlled substances, in violation of 21 U.S.C. § 841(a)(1) (the "distribution charges"). More specifically, of the forty-two distribution charges in the indictment, Dr. Jackson was charged with five counts of distributing OxyContin, Oxy IR, and Percocet (Counts 9 through 13); Dr. Bordeaux with four counts of distributing OxyContin and Oxy IR

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[1] Our citations to "J.A. _" refer to the contents of the Joint Appendix filed by the parties in these appeals.

(Counts 30 through 33); and Dr. Alerre with eight counts of distributing OxyContin (Counts 34 through 41).[2]

A.

The defendants' jury trial was conducted in Florence, South Carolina, from January 27 to February 10, 2003. The jury heard the testimony of fifty-four witnesses, thirty of whom were called by the Government. The most important prosecution witness was Dr. Woodward, who had earlier pleaded guilty under a plea agreement and was cooperating with the United States Attorney.

According to Dr. Woodward's testimony, CCPMC was simply a front for an illegal prescription-selling operation and a health-care-fraud scheme. Woodward explained how he had developed a plan to conceal CCPMC's illegal activities from the law enforcement and medical authorities. In carrying out his activities, he had directed CCPMC physicians to conduct superficial physical examinations of CCPMC patients that served no

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[2] OxyContin, Oxy IR, and Percocet are brand names for drugs containing oxycodone, a Schedule II controlled substance. See 21 C.F.R. § 1308.12(b)(1)(15). Schedule II controlled substances have three defining characteristics: (A) "a high potential for abuse"; (B) "a currently accepted medical use in treatment. . . or a currently accepted medical use with severe restrictions"; and (C) a possibility that abuse "may lead to severe psychological or physical dependence." 21 U.S.C. § 812(b)(2).

medical purpose and were intended only to make the issuance of prescriptions look like the practice of medicine. Tr. 790.[3] In so doing, Dr. Woodward developed a medical record template with boilerplate diagnoses that could be loaded into patients' charts and used to deceive insurance companies and investigators. Tr. 792. Patients were given various diagnostic tests to justify insurance billings, and CCPMC physicians systematically requested outside radiologists to "over read" magnetic resonance imaging pictures in order to justify specific prescriptions. Tr. 798-99. If a patient was insured, the CCPMC doctors would order additional unnecessary tests and scans. Tr. 799.[4] The revenue from such tests and scans constituted about half of CCPMC's income, with the other half being derived from the superficial patient examinations and the issuance of illegitimate prescriptions. *Id.*

In his testimony, Dr. Woodward acknowledged that fifteen to twenty percent of CCPMC's patients had legitimate medical problems, but asserted that all

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[3] Because the Joint Appendix does not contain portions of the trial record relied upon by the Government, we refer to the pertinent parts of the trial transcript, omitted from the Joint Appendix, as "Tr. ____."

[4] The indictment did not charge the defendants with any substantive offenses related to health care fraud. One of the three unlawful activities specified in the laundering conspiracy charge, however, included the submission of false claims to health care benefit programs, in contravention of 18 U.S.C. § 1347.

patients were "treated the same" – i.e., "[t]hey all received the narcotic medication" – without regard to medical necessity. Tr. 887. The testimony of former CCPMC employees and patients corroborated Woodward's evidence.

Dr. Woodward hired Dr. Jackson in February 1998, and hired Dr. Bordeaux two years later, in February 2000. The evidence revealed that Bordeaux and Jackson, along with other CCPMC physicians, developed a practice known as "fast tracking," which they used to expedite the issuance of illegitimate prescriptions for controlled substances. Tr. 399-400. Under the fast-tracking practice, a CCPMC physician would enter an examination room where five or six patients waited, sign prescriptions for each, and promptly exit without asking any medical questions or performing any medical examinations. *Id.*

After Drs. Bordeaux and Jackson left CCPMC in the summer of 2000, Dr. Woodward hired Dr. Alerre. According to Woodward, he needed Alerre to "shadow" him and issue prescriptions because Woodward's license to prescribe controlled substances had been suspended by the DEA. Tr. 818. Woodward further testified that Alerre understood his role before he accepted a position with CCPMC. *Id.* When Alerre began his work at CCPMC, he would accompany Woodward while superficial patient examinations were conducted. Tr. 819. At the conclusion of such examinations, Alerre would issue illegitimate prescriptions to the patients. Tr. 820.

Donald Shafer, a former CCPMC patient, testified that, on his first visit to CCPMC, Drs. Alerre and

Woodward took him to an examination room, searched him to determine if he was wired, and asked if he was working as an undercover agent. J.A. 581-82. Once satisfied that Shafer was not working for the authorities, Woodward and Alerre asked Shafer if he wanted a prescription for OxyContin or a drug called Lorcet. J.A. 584.

Importantly, Dr. Woodward also testified that he confronted each defendant and inquired whether they understood the illicit nature of CCPMC's activities. The defendants assured Woodward that they were willing to participate in CCPMC's overall scheme. Woodward approached Dr. Jackson, asked if he was "able to do this," and Jackson assured him "I got your back." Tr. 792. In answering a similar inquiry, Dr. Bordeaux replied "if I go along with this and do this, can I have your father's pickup truck?" Tr. 815. When Woodward asked Dr. Alerre if he was comfortable with "what we were doing," Alerre paused and responded "[o]h, to hell with it." Tr. 823. Woodward understood Alerre's response to confirm that Alerre was "part of our team"; that is, Alerre was agreeing to join in Woodward's illicit operations. *Id.*

B.

The prosecution's expert witness, Dr. Arthur Jordan, testified that the defendants systematically wrote prescriptions that "were not issued for a legitimate medical purpose." J.A. 819. Based on his review of eighty-eight randomly selected patient charts, Jordan opined that the defendants had failed to adhere to

generally accepted medical standards. *See* J.A. 757, 789-813. Specifically, Jordan testified that many of the prescriptions lacked appropriate documentation or had no "follow up" treatment, that the defendants ignored "red flags" indicative of drug abuse, and that certain prescriptions and dosages were inappropriate. *See* J.A. 789-813.

Dr. Jordan then testified that the defendants had issued prescriptions that were "totally away from and inconsistent with the dosages that a prudent physician in the state of South Carolina would give, as what we call the standard of care." J.A. 815. When the court, *sua sponte*, expressed concern that such evidence might be improper, a defense lawyer stated that he was waiting for Jordan to finish his answer. J.A. 816. The court then observed there was "no reason to put something in the record which the jury may [consider] . . . that is not the standard." *Id.* The court concluded, in the presence of the jury, that "[w]hether the doctors are negligen[t] or not, whether they were guilty of malpractice, is not an issue in this case." *Id.*

The prosecution presented other evidence that the defendants' prescription practices constituted "illegitimate medicine," and that their practices consistently failed to meet the ordinary "standard of care." Though the defense lawyers did not object to such evidence, the court expressed its concern that standard-of-care evidence might be irrelevant and confusing, in that it appeared to relate to civil negligence issues and not necessarily to whether the defendants had contravened the applicable criminal statutes. The

prosecutors, as well as the defense lawyers, repeatedly assured the court that such evidence was relevant and appropriate.

After the prosecution rested its case-in-chief, the defendants presented their own evidence. Dr. Alerre testified personally and called eight other witnesses to testify. Alerre asserted that he had only prescribed medicine to patients he believed to be in pain, and he denied having agreed to participate in CCPMC's illegal activities. Dr. Jackson testified that he had always prescribed medicine in good faith, and he called a corroborating witness. Dr. Bordeaux did not testify, but called thirteen witnesses of her own.

At the close of trial, the court instructed the jury without objection. The instructions included the elements of the various offenses charged, the legal propriety of a physician's actions concerning prescriptions, and the availability of a good faith defense on the distribution and drug conspiracy charges. Tr. 2393; J.A. 1297-99. In particular, the court instructed the jury that it could not convict on the distribution and drug conspiracy charges if it found only that the defendants' practices fell "below that line of what a reasonable physician would have done." J.A. 1299.[5] The instructions were that, in order to

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[5] More specifically, on the standard of care issue, the instructions provided by the trial court were as follows:

There has been some mention. . . of the standard of care. I'm not so sure the word[ ] malpractice ha[s] not been used. Those words relate to civil actions. When you see a doctor, as a patient, that doctor must treat you in a way

convict on the distribution and drug conspiracy charges, the jury was obliged to find beyond a reasonable doubt that the defendants were selling drugs, or conspiring to do so, and not practicing medicine. *Id.* By its verdict, the jury found each defendant guilty as charged, except that Dr. Alerre was found not guilty on one distribution charge (Count 37) and the Government dismissed a distribution charge against Dr. Bordeaux (Count 33).

C.

The laundering conspiracy charge alleged that the defendants conspired with Dr. Woodward and others "to knowingly and willfully conduct and attempt to conduct financial transactions affecting interstate and foreign commerce with the intent to promote the carrying on of specific unlawful activities." J.A. 103. It further alleged that in excess of $5,000,000 was received through CCPMC's heath-care-fraud scheme (i.e., ordering

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so as to meet the standard of care that physicians of similar training would have given you under the same or similar circumstances. . . .

That's not what we're talking about. We're not talking about these physicians acting better or worse than other physicians. We're talking about whether or not these physicians prescribed a controlled substance outside the bounds of their professional medical practice.

J.A. 1299.

unnecessary tests to collect insurance) and its prescription-selling operation, and that such monies were deposited into accounts held and controlled by Woodward and his companies. J.A. 103-04. It alleged that these monies were expended to continue CCPMC's health-care-fraud scheme and prescription-selling operation, and that, "[i]n furtherance of the conspiracy, and to achieve the objectives thereof," payments were made from the illicitly obtained funds, held by Woodward and his companies, to the defendants, Woodward, other CCPMC employees, and other institutions. J.A. 101-06.[6]

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[6] More specifically, the laundering conspiracy charge, a violation of 18 U.S.C. § 1956(h), alleged in part:

> From about June 1997, and continuing until. . . July 2001 . . . [the defendants and others] did . . . knowingly . . . conspire . . . to knowingly and willfully conduct and attempt to conduct financial transactions affecting interstate. . . commerce with the intent to promote the carrying on of specific unlawful activities, that is: causing controlled substances to be dispensed outside the usual course of medical practice and for other than legitimate medical purposes, in violation of [21 U.S.C. § 841]; to defraud health care benefits programs by submitting false claims, in violation of [18 U.S.C. § 1347]; and laundering money with the intent to promote the carrying on of these unlawful activities, in violation of [18 U.S.C. § 1956(a)(1)(A)(i)].

At trial, the parties stipulated that "the checks drawn on the business accounts of [Woodward and his companies], which are referred to in [the laundering conspiracy charge], were cashed, and were financial transactions affecting interstate commerce." J.A. 672-a to 673. As explained above, Woodward's testimony was that each of the defendants had knowingly agreed to participate in CCPMC's illegal activities relating to illegitimate prescriptions and health care fraud.

At the close of the prosecution's case-in-chief, and again at the conclusion of the evidence, the defendants each moved under Rule 29 of the Federal Rules of Criminal Procedure for judgment of acquittal on the laundering conspiracy charge. J.A. 982-84; Tr. 2256-57.[7] Their Rule 29 motions were denied and the jury found each of them guilty on that charge.

D.

On February 17, 2004, prior to the Supreme Court's decisions in *Blakely v. Washington*, 542 U.S. 296

J.A. 103. In its paragraphs 3 and 4, the laundering conspiracy charge identified more than eighty transactions as specific overt acts that were performed in furtherance thereof. *See* J .A. 101-06.

[7] The defendants moved at trial for judgment of acquittal on all counts, but on appeal assert only that they were entitled to such an acquittal on the laundering conspiracy charge.

(2004), and *United States v. Booker*, 125 S. Ct. 738 (2005), the defendants' sentencing hearings were conducted and their sentences were imposed. On appeal, the Government concedes that – because the challenged sentences were premised on drug quantities neither found by the jury nor admitted by the defendants, and because the sentences were imposed under a mandatory Sentencing Guidelines regime – the defendants are entitled to be resentenced. See *Booker*, 125 S. Ct. 738; *United States v. Hughes*, 401 F.3d 540, 555-56 (4th Cir. 2005) (concluding error was plain and warranted reversal where court imposed sentence under mandatory Guidelines based on judicial factfinding, increasing sentencing range beyond that which could have been imposed on the basis of facts found by jury or admitted by defendant).

The defendants have filed timely notices of appeal, and we possess jurisdiction pursuant to 28 U.S.C. § 1291. Their consolidated appeals present three issues:

- First, whether a civil liability standard was erroneously injected into the trial by the prosecutors and the defense lawyers, and, if so, whether the defendants are entitled to relief from their convictions either because their lawyers were constitutionally ineffective, or because the prosecutors engaged in prejudicial prosecutorial misconduct;
- Second, whether the evidence was sufficient to support their convictions on the laundering conspiracy charge; and

- Third, whether the defendants – as the prosecution concedes – are entitled to resentencing because *Booker* was contravened.

As explained below, we reject the defendants' challenges to their convictions, but we vacate their sentences and remand.

II.

A.

First, the defendants contend that they are entitled to a new trial because their lawyers were constitutionally ineffective and because the prosecutors engaged in prejudicial prosecutorial misconduct. These claims derive from their assertion that the lawyers on both sides of the case erroneously and unconstitutionally misunderstood and misapplied the pertinent standard for criminal liability.

1.

We may consider an ineffective assistance claim in the first instance on direct appeal only if it conclusively appears from the record that counsel was constitutionally ineffective. *United States v. Vinyard*, 266 F.3d 230, 333 (4th Cir. 2001); see also *United States v. Russell*, 221 F.3d 615, 619 (4th Cir. 2000) ("A defendant . . . may raise an ineffective assistance claim in the first instance on direct appeal only where the ineffectiveness 'conclusively appears' from the record."). In order to show such

ineffectiveness, a defendant is obliged to demonstrate that (1) the performance of his lawyers "was deficient in that it fell below an objective standard of reasonableness and outside the wide range of professionally competent assistance," and (2) he was actually prejudiced "in that but for counsel's unprofessional errors, the result of the proceeding would have been different." *Swisher v. True*, 325 F.3d 225, 232 (4th Cir. 2003) (internal quotation marks omitted); *accord Strickland v. Washington*, 466 U.S. 668, 691 (1984).

When asserting a prosecutorial misconduct claim, a defendant bears the burden of showing (1) that the prosecutors engaged in improper conduct, and (2) that such conduct prejudiced the defendant's substantial rights so as to deny the defendant a fair trial. See *United States v. Mitchell*, 1 F.3d 235, 240 (4th Cir. 1993). And we review for plain error a prosecutorial misconduct claim that was not raised or presented to the trial court. Fed. R. Crim. P. 52(b); see also *Vinyard*, 266 F.3d at 324 (applying plain error review to prosecutorial misconduct claim first raised on appeal). In reviewing for plain error, we must affirm unless an appellant can show that (1) an error was made, (2) it was plain, and (3) it affected the appellant's substantial rights. *Vinyard*, 266 F.3d at 324. Moreover, the correction of plain error lies within our discretion, which we do not exercise "unless the error seriously affects the fairness, integrity, or public reputation of judicial proceedings." *Id.* at 324-25 (alteration and internal quotation marks omitted).

2.

a.

In order to resolve the ineffective assistance and prosecutorial misconduct claims raised here, we must first assess the proper relationship between the civil and criminal standards of liability for a physician who has prescribed drugs. The distribution charges against the defendants involve violations of 21 U.S.C. § 84l(a)(1), while the drug conspiracy charge involves a violation of 21 U.S.C. § 846, having as its object the contravention of § 84l(a)(1).[8] In relevant part, § 841(a)(1) provides that "[e]xcept as authorized by [law], it shall be unlawful for any person [to] knowingly or intentionally . . . distribute . . . a controlled substance." Generally, in order to convict under § 841(a)(1), the prosecution is obliged to prove "that (1) [the] defendant knowingly or intentionally distributed the controlled substance alleged in the indictment, and (2) at the time of such distribution the defendant knew that the substance distributed was a controlled substance under the law." *United States v. Tran Trong Cuong*, 18 F.3d 1132, 1137 (4th Cir. 1994). An enhanced analysis applies, however, to persons who are

---

[8] Section 846 of Title 21 provides, in pertinent part, that "[a]ny person who . . . conspires to commit any offense defined in this subchapter shall be subject to the same penalties as those prescribed for the offense, the commission of which was the object of the . . . conspiracy."

properly registered with the DEA. Pursuant to 21 U.S.C. § 822, such persons – including doctors – are authorized to distribute controlled substances to the extent authorized by their registrations. See § 822(a) (requiring persons who distribute controlled substances to obtain annual registration from Attorney General); § 822(b) (authorizing registrant to distribute controlled substances "to the extent authorized by the[ ] registration and in conformity with . . . other provisions of [law]"); 28 C.F.R. § 0.100 (delegating, inter alia, Attorney General's authority under § 822 to DEA Administrator).

The seminal decision explaining the liability of such registered distributors is *United States v. Moore*, where the Supreme Court held that a DEA registration under § 822 grants only "a qualified authorization of certain activities, [and] not a blanket authorization" to dispense controlled substances. See 423 U.S. 122, 131 (1975). The defendants in *Moore* – physicians who, although registered with the DEA pursuant to § 822, were convicted under § 841(a)(1) for illegally distributing controlled substances – contended on appeal that, as § 822 registrants, they were immune from liability under § 841. The Court disagreed, affirming their drug distribution convictions and holding "that registered physicians can be prosecuted under § 841 when their activities fall outside the usual course of professional practice." *Id.* at 124 (the "criminal standard"). In discussing the proper application of the criminal standard, we have observed that "a licensed physician who prescribes controlled substances outside the bounds of his professional medical practice is subject to

prosecution and is no different than a large-scale pusher." *Tran Trong Cuong*, 18 F.3d at 1137 (internal quotation marks omitted). In contrast to the criminal standard, a medical malpractice plaintiff in South Carolina must show in a civil case (1) "the generally recognized practices and procedures that would be exercised by competent practitioners in a defendant doctor's field of medicine under the same or similar circumstances," and (2) "that the defendant doctor departed from the recognized and generally accepted standards, practices, and procedures." *Gooding v. St. Francis Xavier Hosp.*, 487 S.E.2d 596, 599 (S.C. 1997) (the "civil standard").

In our 1994 *Tran Trong Cuong* decision, we spelled out the proper relationship between the criminal standard, on the one hand, and the civil standard, on the other. Tran, a registered physician, had been convicted on several distribution charges under § 841(a)(1). See *Tran Trong Cuong*, 18 F.3d at 1133. He sought relief from his convictions by, inter alia, contending that the prosecution's evidence was insufficient. *Id.* at 1137. As part of his contention, Tran asserted that the trial court had, in conducting his trial, mistakenly and erroneously applied the civil standard instead of the criminal standard. *Id.*

We responded to Tran's appeal by explaining the pertinent distinctions between the criminal standard and the civil standard. In particular, Judge Chapman's opinion observed that a criminal prosecution requires "proof beyond a reasonable doubt that the doctor was acting outside the bounds of professional medical practice." *Tran Trong Cuong*, 18 F .3d at 1137. It

elaborated that, in such a situation, a physician's authority to prescribe drugs is being used "not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose, i.e. the personal profit of the physician." *Id.* We concluded that the instructions in Tran's trial not only comported with the criminal standard, but also required the prosecution to prove that the physician had written prescriptions "without a legitimate medical purpose," arguably a more stringent requirement than the criminal standard announced in *Moore*, inuring "to [the] defendant's benefit." *ld.* at 1137-38.

Importantly, as Judge Chapman explained in *Tran Trang Cuong*, we found sufficient evidence to sustain Tran' s distribution convictions by relying in part on expert testimony that Tran had deviated drastically from accepted medical standards. *Id.* at 1138-40. As *Tran Trong Cuong* thus demonstrates, evidence that a physician's performance has consistently departed from accepted professional standards supports the proposition that the physician was not practicing medicine, but was instead cloaking drug deals under the guise of a professional medical practice. As a result, such evidence may properly be relevant to establish that the physician contravened the criminal standard of liability. *See id.*

b.

The defendants contend that the lawyers on both sides of this case erroneously conflated the criminal standard with the civil standard and that, as a result, they were tried and convicted for civil malpractice rather than for the criminal distribution of drugs. Importantly, however, the defendants have neither challenged the sufficiency of the trial evidence nor the propriety of the jury instructions of the trial court.[9] Indeed, the defendants do not point to any specific trial error that

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[9] The instructions in this case are only distinguishable from those we approved in *Tran Trang Cuong* in that the trial court here more clearly articulated the distinction between the civil standard and the criminal standard. *See Tran Trong Cuong*, 18 F.3d at 1137-38. In addition to reciting the *Tran Trong Cuong* instructions nearly verbatim, the court cautioned the jury about the standard-of-care evidence, J.A. 1299, and explained the degree of proof (i.e., proof beyond a reasonable doubt) necessary for a criminal conviction, Tr. 2390. The court further instructed the jury that "[i]f you find that a defendant acted in good faith in dispensing the drugs charged . . . , then you must find that defendant not guilty." J.A. 1298. The court then addressed the standard-of-care evidence and instructed the jury that the critical issue on the distribution and drug conspiracy charges was not whether the defendants had acted negligently, but "whether or not these physicians prescribed a controlled substance outside the bounds of their professional medical practice." J.A. 1299.

prejudiced them. Rather, they contend that their entire trial was infected with an erroneous standard of proof and that the verdict must thus be set aside, notwithstanding the sufficiency of the evidence and the propriety of the jury instructions. As explained below, this position does not pass muster.

First, the defendants have not directed us to any evidence that was improperly introduced. In contending that they were erroneously tried, the defendants appear to be asserting that, because standard-of-care evidence might show that a physician contravened the civil standard, it must categorically be excluded from a criminal proceeding. As our analysis in *Tran Trang Cuong* demonstrates, however, evidence that a physician consistently failed to follow generally recognized procedures tends to show that in prescribing drugs he was not acting as a healer but as a seller of wares. *See* 18 F .3d at 1138-40; *see also* Fed. R. Evid. 401 ("'Relevant evidence' means evidence having any tendency to make the existence of any fact that is of consequence . . . more probable or less probable than it would be without the evidence."); Fed. R. Evid. 402 (providing that relevant evidence is generally admissible).[10]

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[10] To be sure, an undue emphasis on standard-of-care evidence might, in certain circumstances, confuse a jury. *See* Fed. R. Evid. 403 ("Although relevant, evidence may be excluded if its probative value is substantially outweighed by the danger of unfair prejudice, confusion of the issues, or misleading the jury. . . .").

Second, as the defendants concede, the jury was correctly instructed on the applicable legal principles. The trial court was careful to spell out the differences between the criminal standard and the civil standard. Indeed, it admonished the jury that the defendants could only be convicted under the criminal standard, and it emphasized that they could not be convicted if they had dispensed the controlled substances at issue "in good faith." Ordinarily, of course, we presume that a properly instructed jury has acted in a manner consistent with the instructions. *See Jones v. United States*, 527 U.S. 373, 394 (1999). Nonetheless, the defendants maintain that, on this record, an overwhelming probability exists that the jury ignored the instructions and convicted the defendants of civil malpractice. *See Goldsmith v. Witkowski*, 981 F.2d 697, 703 (4th Cir. 1992) ("The presumption of cure by a court's instructions is overcome when there is an overwhelming probability that the jury will be unable to follow the court's instructions, and a strong likelihood that the effect of the [trial error] would be devastating to the defendant." (internal quotation marks omitted)). In these circumstances, we are unable to agree with the defendants. The jury entered its deliberations armed with ample admissible evidence and with proper instructions on the applicable legal principles. The defendants' assertions that their lawyers were confused at trial is insufficient to rebut the presumption that the jury used these tools properly.[11]

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[11] Even if the defendants could show error with respect to their standard-of-proof assertions, it would be difficult to

In these circumstances, the defendants have not established any trial error caused by a misapprehension of the criminal standard on the part of the lawyers. They are unable to show that a substandard performance by their lawyers conclusively appears from the record, and they have also failed to demonstrate that the prosecutors engaged in any improper conduct relating to the standard of proof or their use of evidence. Accordingly, we decline to reach and address the defendants' ineffective assistance claims, and we reject their prosecutorial misconduct claims on the merits.

B.

Next, the defendants contend that the evidence was insufficient to support their convictions on the laundering conspiracy charge and that the district court therefore erred in denying their motions, pursuant to Rule 29 of the Federal Rules of Criminal Procedure, for judgment of acquittal on that charge. The defendants' contention on this point is premised on their view that, as a matter of law, a defendant must have committed the substantive offense of promotion money laundering in

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conclude that they were thereby prejudiced. Indeed, Dr. Woodward's testimony alone was sufficient to convict the defendants, and it was supported by other evidence. And in light of its verdict, we assume that the jury credited Woodward's testimony. *See United States v. Hughes*, 401 F.3d 540, 544-45 (4th Cir. 2005).

order to be convicted on the laundering conspiracy charge. As explained below, that proposition is legally incorrect. Moreover, the jury was properly instructed – without objection – on the laundering conspiracy charge, and the defendants' convictions on that offense are supported by substantial evidence.[12]

1.

We review de novo a district court's denial of a Rule 29 motion for judgment of acquittal. *United States v. Ryan-Webster*, 353 F.3d 353, 359 (4th Cir. 2003).[13] In so

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[12] The defendants also maintain on appeal that, as a predicate to convicting them on the laundering conspiracy charge, the jury was obliged to find that they had contravened the criminal standard in prescribing controlled substances. In so doing, they reassert their ineffective assistance and prosecutorial misconduct claims in attacking their convictions on the laundering conspiracy charge. As explained above, *see supra* Part II.A, we are unable to grant relief on either of those claims, and we thus need not address whether they might have entitled the defendants to relief on the laundering conspiracy charge.

[13] Pursuant to Rule 29(a), "[a]fter the government closes its evidence or after the close of all the evidence, the court on the defendant's motion must enter a judgment of acquittal of any offense for which the evidence is insufficient to sustain a conviction." A Rule 29 determination thus focuses on both the elements of the offense charged and on the tactual sufficiency of the

doing, we are obliged to sustain a guilty verdict if, viewing the evidence in the light most favorable to the Government, it is supported by "substantial evidence." *United States v. Burgos*, 94 F.3d 849, 862 (4th Cir. 1996) (en banc) (citing *Glasser v. United States*, 315 U.S. 60, 80 (1942)). We have defined "substantial evidence" as "evidence that a reasonable finder of fact could accept as adequate and sufficient to support a conclusion of a defendant's guilt beyond a reasonable doubt." *Id.* Moreover, in conducting such a review, we must "remain cognizant . . . that the jury, not the reviewing court, weighs the credibility of the evidence and resolves any conflicts in the evidence presented." *Id.* (internal quotation marks omitted).

2.

The laundering conspiracy charge is, in substance, that the defendants contravened 18 U.S.C. § 1956(h) by conspiring with Dr. Woodward and others to commit promotion money laundering, as defined in 18 U.S.C. § 1956(a)(1)(A)(i). By its terms, the promotion money laundering provision – the violation of which was the object of the laundering conspiracy charge – requires the prosecution to (1) trace the money at issue to an underlying unlawful activity, and (2) prove that the money was transferred in order to promote a specified

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evidence.

unlawful activity. *See* § 1956(a)(1)(A)(i).[14] In previously addressing a promotion money laundering issue, we found the promotion element satisfied when a defendant paid his subordinate employee for being involved in an unlawful scheme, because such payments compensated the employee for his illegal activities and encouraged his continued participation. *United States v. Bolden*, 325 F.3d 471, 489 (4th Cir. 2003).

Pursuant to § 1956(h), the laundering conspiracy statute, "[a]ny person who conspires to commit any offense defined in [§ 1956] . . . shall be subject to the same penalties as those prescribed for the offense the commission of which was the object of the conspiracy." Thus, in order for the jury to convict on the laundering conspiracy charge, the prosecution was obliged to prove that (1) a conspiracy to commit promotion money laundering was in existence, and (2) that during the conspiracy, the defendant knew that the proceeds used to

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[14] The offense of promotion money laundering stands in contrast to the offense of "concealment money laundering," as defined and prohibited by § 1956(a)(1)(B)(i). While both offenses require the prosecution to trace the funds at issue to a specified unlawful activity, a defendant commits promotion money laundering by transferring the funds "to promote the carrying on of specified unlawful activity," see § 1956(a)(1)(A)(i), whereas concealment money laundering is committed by transferring such funds "to conceal or disguise" their illegal origins, *see* § 1956(a)(1)(B)(i).

further CCPMC's illicit operations had been derived from an illegal activity, and knowingly joined in the conspiracy. *See United States v. Diamond*, 378 F.3d 720, 727 (7th Cir. 2004) ("To convict a defendant of conspiracy to commit money laundering, the government must show the defendant was involved with two or more people to launder money and that the defendant knew the proceeds used to further the scheme were derived from an illegal activity."). As explained below, substantial evidence supports each of these elements, and the district court properly denied the defendants' requests for judgments of acquittal on the laundering conspiracy charge.

a.

First, the defendants challenge their convictions on the laundering conspiracy charge by contending that the evidence was insufficient to find them guilty of promotion money laundering. This contention misses the point: As a factual matter, the defendants were neither charged with nor convicted of promotion money laundering. Rather, they were charged with and convicted of *conspiring* to commit promotion money laundering. As a legal matter, the prosecution was not required to prove that the defendants had committed promotion money laundering in order to convict them of conspiring to do so. *See Diamond*, 378 F.3d at 727. Accordingly, we need not – and do not – reach the issue of whether the evidence in this case would have supported their convictions on the substantive offense of promotion money laundering. *Cf. United States v. Heaps*, 39 F.3d

479, 486 (4th Cir. 1994) (concluding that simple drug transaction did not constitute promotion money laundering where no evidence showed that proceeds from transaction were subsequently used to promote unlawful activity), *recognized as abrogated on other grounds by United States v. Villarini*, 238 F.3d 530, 534-35 (4th Cir. 2001). Our inquiry is thus limited to whether the trial evidence was sufficient to sustain the defendants' convictions for conspiracy to commit promotion money laundering.

b.

Second, the defendants have not assigned error to the court's instructions on the laundering conspiracy charge, and they interposed no objection to those instructions at trial. The court instructed the jury that, in order to convict on that charge, it was obliged to find beyond a reasonable doubt as to each defendant: (1) that the conspiracy alleged existed; (2) that "at some time during the . . . life of the conspiracy . . . the defendant knew the purpose of the agreement and then deliberately joined the conspiracy"; and (3) that "[a]t some point during the . . . life of the conspiracy . . . one of its alleged members knowingly performed one of the overt acts charged in order to further or advance the purpose of the conspiracy." Tr. 2413. The court also explained to the jury the essential elements of the offense of promotion money laundering, which was the object of the laundering conspiracy charge. Tr. 2413-15.

Not only have the defendants failed to assign error to the instructions, the trial court arguably added an unnecessary element to the § 1956(h) offense, favoring the defendants. The court instructed the jury that it could not convict on the laundering conspiracy charge without finding that a conspirator had committed an overt act in furtherance of the conspiracy. *Compare* Tr. 2413 (instructing on overt act requirement for § 1956(h)) *with Whitfield v. United States*, 125 S. Ct. 687, 691 (2005) (holding that § 1956(h) has no overt act element), *and Bolden*, 325 F.3d at 491 (same). In sum, there were no objections to the relevant instructions, and the only possible error in those instructions was to the benefit of the defendants.[15]

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[15] Although not an issue on appeal, the instructions on the unlawful activity aspect of the object of the laundering conspiracy charge varied from the indictment. As explained above, the object of the conspiracy in that charge was promotion money laundering. The laundering conspiracy charge identified three specific unlawful activities that the conspiracy sought to promote: (1) the unlawful distribution of controlled substances (21 U.S.C. § 841); (2) health care fraud (18 U.S.C. § 1347); and (3) promotion money laundering (18 D.S.C. § 1956(a)(1)(A)(i)). J.A. 103. The court instructed, however, that the "specified unlawful activity is the *conspiracy* to distribute or dispense controlled substances." Tr. 2416 (emphasis added). There was no objection to this instruction, perhaps because the defendants believed it to be advantageous to them. In any event, it would plainly appear to be a non-fatal variance. *See United States v. Davis*, 202 F.3d 212, 216 n.3 (4th Cir. 2000) ("[A] non-

c.

Finally, there was substantial evidence presented to the jury supporting the defendants' convictions on the laundering conspiracy charge. According to Dr. Woodward's evidence, the defendants agreed to participate with him and others in carrying on CCPMC's unlawful operations (the prescription-selling and health-care-fraud schemes). The conspiracy the defendants joined called for Woodward and his companies to acquire funds through CCPMC's illegal activities and then distribute those funds to CCPMC's physicians, employees, and owners (including the defendants), as compensation for their efforts; that is, the scheme called for Woodward to commit promotion money laundering. *Cf. Bolden*, 325 F.3d at 489 (concluding that promotion money laundering conviction was supported by evidence that defendant paid subordinate for participation in illegal scheme because such payment compensated subordinate for past illegal activities and encouraged his future participation).[16] Unfortunately for the defendants,

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prejudicial variance between the indictment and the proof that does not modify the elements of the charged offense is no basis to invalidate a conviction.").

[16] In their Reply Brief, the defendants concede that the *Bolden* principles "might support a promotion [money laundering] claim against Dr. Woodward," but nonetheless contend that it cannot "support[ ] a promotion [money laundering] claim against Drs. Alerre,

they cannot, as a legal proposition, divorce themselves from the reasonably foreseeable acts which Woodward committed in furtherance of the conspiracy while they were members thereof. *See United States v. Newsome*, 322 F.3d 328, 338 (4th Cir. 2003) ("[U]nder conspiracy law, [a conspirator] is liable for the conduct of all co-conspirators that was in furtherance of the conspiracy and reasonably foreseeable.") (citing *Pinkerton v. United States*, 328 U.S. 640, 646-47 (1946)).

Dr. Woodward's evidence, if credited by the jury, thus established the essential elements, as spelled out in the instructions, for conviction of the defendants on the laundering conspiracy charge: (1) that there was a conspiracy to commit promotion money laundering; (2) that during the life of the conspiracy, each defendant knew the purpose thereof and then deliberately joined in it; and (3) that during the conspiracy, a conspirator performed at least one of the overt acts alleged in furtherance thereof. Crediting Woodward's testimony, as we must, the convictions on the laundering conspiracy charge are supported by substantial evidence.

C.

In their third and final appellate contention, the defendants maintain they are entitled to resentencing under *United States v. Booker*, 125 S. Ct. 738 (2005), and

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Bordeaux, and Jackson." Reply Br. at 15. As related above, this contention is beside the point.

its progeny. In its brief, in its supplemental letter of April 15, 2005 to this Court, and again at oral argument, the prosecution has conceded error on this issue and agreed that *Booker* mandates resentencing of the defendants. The prosecution's position is valid, and we therefore vacate the defendants' sentences and remand for such resentencing proceedings as may be appropriate.[17]

III.

Pursuant to the foregoing, we affirm the defendants' convictions, vacate their sentences, and remand.

AFFIRMED IN PART,
VACATED IN PART, AND REMANDED

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[17] As in *United States v. Hughes*, "[w]e of course offer no criticism of the district judge, who followed the law and procedure in effect at the time of [the defendants'] sentencing." See 401 F.3d 540, 545 n.4 (4th Cir. 2005).

APPENDIX B

UNITED STATES COURT OF APPEALS
FOR THE FOURTH CIRCUIT

FILED
December 28, 2005

No. 03-4207
CR-02-673

UNITED STATES OF AMERICA
Plaintiff - Appellee

v.

RICARDO U. ALERRE
Defendant - Appellant

No. 03-4212
CR-02-673

UNITED STATES OF AMERICA
Plaintiff - Appellee

v.

DEBORAH BORDEAUX
Defendant - Appellant

No. 04-4161
CR-02-673

UNITED STATES OF AMERICA
Plaintiff - Appellee

v.

MICHAEL D. JACKSON
Defendant - Appellant

On Petition for Rehearing and Rehearing En Banc

The appellants' petition for rehearing and rehearing en banc was submitted to this Court. As no member of this Court or the panel requested a poll on the petition for rehearing en banc, and

As the panel considered the petition for rehearing and is of the opinion that it should be denied,

IT IS ORDERED that the petition for rehearing and rehearing en banc is denied.

Entered for a panel composed of Judge Michael, Judge Motz, and Judge King.

For the Court,

/s/ Patricia S. Connor

CLERK

APPENDIX C
JUDGMENT

FILED: December 1, 2005

UNITED STATES COURT OF APPEALS
for the
Fourth Circuit

No. 03-4207
CR-02-673

UNITED STATES OF AMERICA
Plaintiff - Appellee

v.

RICARDO U. ALERRE
Defendant - Appellant

No. 03-4212
CR-02-673

UNITED STATES OF AMERICA
Plaintiff - Appellee

v.

DEBORAH BORDEAUX
Defendant - Appellant

No. 04-4161
CR-02-673

UNITED STATES OF AMERICA
Plaintiff - Appellee

v.

MICHAEL D. JACKSON
Defendant - Appellant

Appeal from the United States District Court for the District of South Carolina at Florence

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In accordance with the written opinion of this Court filed this day, the Court affirms in part and vacates in part the judgment of the District Court. This case is remanded to the District Court for further proceedings consistent with the Court's opinion.

A certified copy of this judgment will be provided to the District Court upon issuance of the mandate. The judgment will take effect upon issuance of the mandate.

/s/ Patricia S. Connor

CLERK

APPENDIX D

Prescription Drug Diversion Prosecutions
Quick Reference Card 2002

We intend this card to serve as a basic guide to prosecuting prescription drug diversion cases. Users should check recent cases and, where necessary, consult with their supervisors before making a final decision regarding charging strategies. For space purposes, we left the "U.S." out of all of our citations. If the cite involves a civil case, we noted the same.

Why Drug Diversion Prosecutions - Civil and Criminal?

■ The Controlled Substances Act, 21/801 *et seq.*, states that "except as provided by this subchapter, it shall be unlawful for any person ***knowingly or intentionally . . . to distribute, or dispense a controlled substance.*** 21/841(a)(1). Section 842(c)(1) authorizes civil penalties for a violation of the act. "In order to enable physicians and certain others (e.g., manufacturers, nurses, and pharmacists) lawfully to distribute or dispense drugs within the course of their professional practice, Congress provided that '[persons registered . . . under this subchapter . . . to the extent authorized by their registration and in conformity with the other provisions of this subchapter.'" 21/822(b). "This exemption from the Act granted to medical practitioners engaged in distribution of controlled substances ***is a limited one***

since practitioners possess increased access to controlled substances and therefore greater opportunities for diversion. *ALN Corp.*, 1993 WL 402803, *2 (D. Conn.) (Civil case), quoting *Vamos*, 797 F.2d 1146, 1152-53 (2d Cir. 1986); *see also Moore*, 423 U.S. 122, 135 (1975); Clinical Leasing Service, Inc., 759 F. Supp. 310, 316-17 (E.D. La. 1990) (civil case). ■ Congress provides an exemption to physicians and other medical practitioners who use their ability to issue controlled substances to heal patients, but allows prosecution of those unscrupulous medical professionals who use these privileges to deal and steal. *See Singh*, 54 F.3d 1182, 1188-89 (4th Cir. 1995) ("Congress gave doctors the power to authorize the distribution of dangerous addictive drugs, and with that power, Congress also places upon [the doctor] the responsibility to distribute them wisely within the course of [the doctor's] medical practice").

Relevant Definitions

■ **Practitioner** means a physician, dentist, veterinarian, scientific investigator, pharmacy, hospital, or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute, dispense, conduct research with respect to, administer, or use in teaching or chemical analysis, a controlled substance in the course of professional practice or research.**21/802(21)**. ■ **Controlled Substance** means a drug or other substance, or immediate precursor, included in Schedule I, II, III, IV, or V of 21/812. **21/802(6)**. ■ **Deliver** means

the actual, constructive, or attempted transfer of a controlled substance or a listed chemical, whether or not there exists an agency relationship.**21/802(8)**. ■ **Dispense** means to deliver a controlled substance to an ultimate user or research subject, by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term "dispenser" means a practitioner who so delivers a controlled substance to an ultimate user or research subject. **21/802(10)**. ■ **Distribute** means to deliver (other than by administering or dispensing) a controlled substance or a listed chemical. The term "distributor" means a person who so delivers a controlled substance or a listed chemical.**21/802(11)**. ■ **Ultimate User** means a person who has lawfully obtained, and who possess[es], a controlled substance for his own use or fur the use of a member of his household or for an animal owned by him or by a member of his household.**21/802(27)**. See *Bartee*, 479 F.2d 484 (10th Cir. 1973) (various definitions).

Basic Element of § 841 Offense

■ The basic elements are: (1) the defendant knowingly or intentionally, (2) distributed or dispensed, (3) a controlled substance. The statutory language of 21/841 does not contain any other elements. However, to prove: that the distribution or dispensation via prescription was illegal, the government must show that there was no legitimate medical purpose for the prescription and the same was

not issued/filled in the usual course of professional practice or was beyond the bounds of medical practice. *Singh*.

When is a Prescription for a Controlled Substance Effective?

■ A prescription for a controlled substance is effective if issued **(1) for a legitimate medical purpose (2) by an individual practitioner (3) acting in the usual course of h is professional practice, 21 C.F.R. §1306.04(a).** ■ The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. ***See Milicia*, 769 F. Supp. 877, 878-80 & n.8 (E.D. Pa.1991), citing § 1306.04(a).** ■ Any individual practitioner who issues or fills a prescription knowing that the prescription was not issued for a legitimate medical purpose in the usual course of professional treatment (or for legitimate and authorized research), shall be subject to penalties provided for violations of the controlled substances law. A conviction will be upheld even if the government does not present compelling evidence that the doctor prescribed with malicious motive or the desire to make a profit. *Singh*, at 1188.

What is a Legitimate Medical Purpose?

■ A physician is acting with a legitimate medical purpose when he or she prescribes medical treatments that are in **strict compliance with well-established and generally accepted medical guidelines, and administers medical treatments that appropriately and correctly address and relieve the present medical condition.** *Tran Trong Coung*, 18 F.3d 1132 (4th Cir. 1994) (reversed and remanded). ■ To decide whether a physician acted without a legitimate medical purpose, you must examine all of the defendant's actions and the circumstances surrounding them. ■ Abbreviated or no medical history or physical examination is probative on the question of whether a legitimate medical purpose exists. *Chin*, 795 F.2d 496, 500 (5th Cir. 1986). ■ Evidence that a doctor tells patients where to get their prescriptions filled, prescribes drugs even after learning of a patient's addiction to them, or asks patients about the amount or type or type of drugs they want, is probative of whether a legitimate medical purpose exists for the dispensed controlled substances. *Singh*, 54 F.3d 1182; *Coung*, 18 F.3d 1132.

What is the Usual Course of Professional Practice?

■ "There are no specific guidelines concerning what is required to support a conclusion that an accused acted outside the usual course of professional practice. Rather, the courts must engage in a case-by-case analysis of evidence to determine whether a reasonable inference of

guilt may be drawn from specific facts." *Singh*, at 1187, quoting *August*, 984 F.2d 705, 713 (6th Cir. 1992), and *Cuong*, at 1137-38, ■ A physician must act in a good faith manner that is in direct accordance with the reasonableness standard set forth in the medical community. *Boettjer*, 569 F.2d 1078, 1080-82 (9th Cir. 1978). ■ A physician must use reasonableness and sound medical discretion in following generally accepted medical guidelines in the administration of correct-medical treatment throughout the physician/patient relationship. *Moore*, 423 U.S. at 139. ■ Licensed physicians who prescribe controlled substances outside bounds of their professional medical practice are subject to prosecution and are no different from large scale drug dealers. **Comprehensive Drug Abuse Prevention Act of 1974, § 401(a), 21 U.S.C.A. § 841(a).** ■ The indictment need not charge that the dispensation was done outside the course of professional practice, *Steele*, 147 F.3d 1316 (11th Cir. 1998) (en banc), citing 2l/885(a)(l), because the government does not have to negate any exemption or exception set forth in Title 21 in the indictment). ■ The better practice, however, is to include this language to familiarize the jury with the concept and make clear your basis for the illegal dispensation and distribution charges. *Roya*, 574 F.2d 386 (7th Cir. 1978).

Deliberate Ignorance/Willful Blindness

■ The government may show knowledge by proof that the physician or pharmacist deliberately closed his or her eyes to the true nature of a prescription. *Lawson*, 682

F.2d 480 (4th Cir. 1982) (pharmacist charged with illegal distribution of controlled substances); *Neville*, 82 F.3d 750, 759-60 (7th Cir. 1996). ■ "When a pharmacist is faced with a large number of prescriptions all written by one doctor and all presented by one person, this constitutes evidence that the prescriptions are not legitimate." *Lawson*, at 482, citing *Hayes*, 595 F.2d 258, 260 (5th Cir. 1979); *see also Milicia*, 769 F. Supp. at 884. ■ "[U]niform dosages and quantities belied any conclusion that the prescriptions . . . were ordered *for individual patients*." 682 F.2d at 482-83 & n6 (discussing expert testimony that uniformity of prescriptions should signal to a pharmacist that the prescriptions were not legitimate). ■The nature of the physician's practice does not match the nature of the prescriptions (proving outside the course of professional practice and lack of legitimate medical purpose). 682 F.2d at 482-83 (giving the example of Dilaudid being used only for those people with excruciating pain, such as with a doctor operating a clinic that treats terminally ill cancer patients). ■ The *Lawson* court held that the evidence proved the defendant pharmacist "willingly ignored every signal that he should question the volume of controlled substances being dispensed from his pharmacies." Id. & n.17, citing *Seelig*, 622 F.2d 207, 213 (6th Cir. 1980) (jury instructions). ■ **Others:** Prescriptions written on a large-scale basis (i.e., over 90% of the prescriptions written by the physician were for controlled substances, a, figure expert testimony will show is outrageously high and dramatically out of line with professional medical practices of other similarly-situated physicians). *Hammond*, 781 F.2d 1536

(11th Cir. 1986). ■ **Consider a pharmacist** expert witness, and have them testify that "pharmacists are not allowed to fill every prescription issued by a licensed physician and they must screen their patients for 'drug-seeking' behaviors." *Sims-Robertson*, 16 F.3d 1223, 1994 WL 12212 (6th Cir. (Mich.) (Unpublished). ■ **See the DEA Pharmacist's Manual** (on their web-site). See also *Leal*, 75 F.3d 219 (6th Cir. 1996) (pill mill case, defendant pharmacist, and "ostrich" instruction approved); *Veal*, 985 (6th Cir. 1994).

Dispense or Distribute or Both?

■ **The case law is not always clear about whether the act of prescribing or filling controlled substances without a legitimate medical purpose and outside the course of professional practice is Illegal Dispensing or Distribution or Both.** ■Here are a few cases illustrating different charging theories. ■**PRESCRIBING:** "Improperly issuing a prescription for a controlled substance is sufficient to warrant a conviction under the [CSA] ***even though the doctor does not himself actually distribute the drugs and even though the prescription is not subsequently filled***. The sheer number of prescriptions written to any individual is proof that the defendant knew he was ***prescribing drugs improperly***. *Cuong*, 18 F.3d at 1139, quoting *Stump*, 735 F.2d 273, 275-76 (7th Cir. 1984). ■ **DISPENSING:** "A doctor's authority to prescribe controlled substances is violated when he uses that authority to assist another in maintaining a drug habit

or when he dispenses controlled substances for other than a legitimate medical purpose. *Singh.* ■ **DISTRIBUTION:** The indictment was not defective because the government charged the defendant with illegal distribution instead of illegal dispensation. *Ellzey*, 527 F.2d 1306 (6th Cir. 1976). ■ **BOTH:** In *Green*, 511 F.2d 1062 (7th Cir. 1975), a physician was charged and convicted of illegal dispensation and a pharmacist was charged and convicted of illegal distribution. In *Hoffman*, 129 F.3d 1196 (11th Cir. 1997), the plea agreement charged both illegal dispensing and distribution. In *Sutherland*, 2001 WL 1502913 (W.D. Va.), the jury convicted the defendant of 427 counts of ***unlawfully dispensing and distributing controlled substances***. In *Dunbar*, 614 F.2d 39, 41 (5th Cir. 1980), the court said "a licensed medical doctor can be prosecuted for the distribution or dispensation of Schedule II controlled substances outside the usual course of professional practice, citing *Moore*, 423 U.S.122. ■ **The "Go-Figure" Winners are:** "[t]o convict a physician of distributing a controlled substance . . ., the government must prove . . . that the defendant 'distributed or dispensed a controlled substance.'" *Singh*, 54 F.3d at 1186-87, quoting *Cuong*, 18 F.3d at 1141; *see also Chin*, 795 F.2d at 499 (diet pill doc). ■ **REAL DISTINCTION?:** Read *Harrison*, 651, F.2d 353 (5th Cir. 1981); *Thompson*, 624 F.2d 740 (5th Cir. 1980); and *Leigh*, 487 F.2d 206 (5th Cir. 1976). ■ **SOLUTION?:** Read ***Moore*, 423 U.S. 122**. You cannot create a hyper-technical distinction between dispense and distribute as both involve delivery. *Fellman*, 549 F.2d

181, 182 (10th Cir. 1977); *see also Badia*, 490 F.2d 296 (1st Cir. 1973); *Rosenburg*, 515 F.2d 190 (9th Cir. 1975).

Unit of Prosecution

■ The unit of prosecution is each act of dispensation or distribution (each prescription written or filled). *Sugar*, 606 F. Supp. 1134 (S.D.N.Y. 1985); *Elliott*, 849 F.2d 886 (4th Cir. 1988).

Death or Serious Bodily Injury

■ If you have evidence of patient overdoses resulting from the physician's prescribing pattern, consider charging the enhances penalty provisions under 21/841(b). There are *Apprendi* issues here.

Expert Witness Issues

■ "Neither the government nor the defendant is required to provide expert testimony on the issue of whether the actions taken by the defendant were or were not for a legitimate medical purpose or in the usual course of professional practice." *Polito*, 111 F.3d 132, 1997 WL 178879, *5 (6th Cir. (Ohio)), quoting *Word*, 806 F.2d 658, 663 (6th Cir. 1993). ■ "There are cases in which the lay testimony is so clear that no expert testimony is required to determine that the defendant's actions were not for a legitimate medical purpose nor in the usual course of professional practice." *Polito* quoting *Word*. ■ Many cases are not that clear cut because the target physician or

pharmacist may also have legitimate patients or fill legitimate prescriptions. ■ **Potential Areas of Expert Testimony:** Signs of addiction and how a physician discovers them. The effects of all of the drugs prescribed, and their proper uses overall, the legal requirements for issuing a prescription, and the inappropriateness of the prescriptions in each § 841 count. The danger of long-term use of narcotic analgesics, which contain acetaminophen, and their toxic nature to the human body. The process of titrating narcotic dosages upward as the body adjusts and develops tolerance to them, and why you do not prescribe high dosages to a patient that is not opioid-tolerant. The distinctions in treating acute, malignant, and chronic, non-malignant pain patients, and the distinctions between abuse, addiction, dependance, and tolerance. Poly-pharmacy or prescribing specific drug combinations – when to and when not to. This is important because many pill docs prescribe in cocktail fashion, i.e., hydrocodone, soma, oxycodone, and Xanax. Note: pain is subjective and requires a specific treatment plan for each patient. This is important because the bad doctors prescribe the same drugs in the same amounts to all or most of their patients, including patients within the same family. Use. a pain specialist to review medical files and provide opinion testimony concerning legitimate medical use of opioid therapy without other non-invasive or invasive therapies. Make sure your expert has reviewed pharmaceutical literature re: drugs at issue and prescribes these drugs in his/her practice. Determine whether your expert has served on the drug manufacturer's speakers' bureau.

Sample Count Table

■ Consider using the following table to set out each substantive dispensation or distribution count in your indictment:

Count	Date	Controlled Substance, Schedule & Form	Number of Pills	Strength
1	7/8/01	Amphetamine (S-II) Adderall®	90	30mg
2	7/10/01	Oxycodone (S-II) OxyContin®	90	40mg
3	7/11/01	Hydrocodone (S-III) Norco®	180	10mg

Sentencing Issues for Pill Cases

■ **Equivalency ratios are used in determining drug weight for sentencing purposes in pill cases.** Thus, "to determine the base offense level, the probation officer [will use] the drug equivalency tables to convert oxycodone, [amphetamine, and hydrocodone] into an equivalent marihuana weight." *Sutherland*, 2001 WL 1502913, *3, discussing sentencing on Schedule II oxycodone and amphetamine. See **OxyContin Sentencing Table**. ■ The "guidelines do not differentiate between oxycodone and its salts," so the

whole weight of the pill counts. *Sutherland*, citing the guidelines and *Soto*, 1 F.3d 920, 922-23 (9th Cir. 1993). ■ **A defendant's special training as a doctor constitutes a special skill used in the commission of [drug diversion] offenses. Same with a pharmacist.** *Sutherland*.

Further Guidance

■ For further guidance on these issues contact the authors:

Jennifer Golen, AUSA-EDTN, jennifer.bolen@usdoj.gov

Randy Ramseyer, AUSA-WDVA, randy.ramseyer@usdoj.gov